

UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ILLINOIS,
EASTERN DIVISION

UNITED STATES OF AMERICA,
ex rel., RICHARD SANCHEZ,

Plaintiffs,

vs.

ABBOTT LABORATORIES, INC., d/b/a)
ROSS PRODUCTS DIVISION OF
ABBOTT LABORATORIES, INC.
and MEDLINE INDUSTRIES, INC.
K

Defendants.

07cv819

JUDGE HOLDERMAN
MAGISTRATE JUDGE BROWN

Civil Action No.

Filed In-Camera and Under Seal

JURY TRIAL DEMANDED

FILED

FEB 12 2007

MICHAEL W. DORRINS
CLERK, U.S. DISTRICT COURT

COMPLAINT

NOW COMES the United States of America, *ex rel.*, RICHARD SANCHEZ, Plaintiff/Relator in the above-captioned matter, by and through his attorneys, and for causes of action against the Defendants states and alleges as follows:

JURISDICTION AND VENUE

1. This action, filed pursuant to the False Claims Act, 31 U.S.C. §3729 *et seq.*, seeks to recover damages and penalties arising out of false claims the Defendants have presented and/or caused to be presented to the United States Government for payments through the federally funded Texas Medicaid Program and, on information and belief, through other states' Medicaid agencies and other federally funded programs.

2. The Relator, Richard Sanchez, is a citizen and resident of the state of Texas and brings this action for himself and on behalf of the United States. He has standing to bring this case pursuant to 31 U.S.C. §3730(b), which allows any person to

bring a claim for himself on behalf of the United States. The facts on which the claims stated herein are based have not been the subject of public disclosure. These facts are set forth in this Complaint and in the Written Disclosure of Substantially All Material Evidence and Information, which is attached hereto as Exhibit A and incorporated by reference as if fully set forth herein. In addition, the Relator is an original source of said facts, in that he has direct and independent knowledge of the information on which the allegations herein are based, and has voluntarily provided the information to the government before filing this action.

3. Abbott Laboratories, Inc. (hereafter "Abbott") is a foreign corporation duly organized and existing under the laws of the state of Delaware, and maintains its principal place of business in Abbott Park, Illinois. Abbott has been at all times pertinent hereto authorized to and has transacted business in the state of Illinois. At all times pertinent hereto, Abbott Laboratories manufactured and distributed through its wholly owned subsidiary, Ross Products, a product known as PediaSure® which is an enteral formula nutritional supplement utilized by patients who are unable to feed themselves. Once this case is unsealed by the court, Abbott may be served with process by serving its registered agent, CT Corporation System at its office located at 208 S. LaSalle Street, Suite 814, Chicago, Illinois 60604.

4. Medline Industries, Inc. (hereafter "Medline") is a domestic corporation duly organized and existing under the laws of the state of Illinois, and maintains its primary place of business in Highland Park, Illinois. Medline is one of America's largest privately held manufacturers and distributors of health care supplies and services. In this regard, Medline has distributed and sold Abbott's enteral formula nutritional supplement product PediaSure® to home health care agencies that purchase PediaSure® through state Medicaid programs for the consumption of disabled individuals requiring enteral nutritional supplements. Once this case is unsealed by the court, Medline may be served with process by serving its registered agent, Richard M. Horwood, at his office located at 180 North LaSalle Street, Suite 3700, Chicago, Illinois 60601.

5. Venue is proper in this district pursuant to 31 U.S.C. §3732(a), in that both Defendants can be found, are authorized to transact business in, and maintain their principal places of business in this district.

FACTUAL ALLEGATIONS

6. Richard Sanchez is the father of a minor son who was born in 1994 and suffers from cerebral palsy. As a result, this child is developmentally delayed with the mental capacity of a 1 to 2 year old. He is unable to speak, feed or care for himself and consumes the food supplement PediaSure® through a gastronomic g-button or g-tube connected to his stomach.

7. Mr. Sanchez' son is a Medicaid patient in the state of Texas and receives PediaSure® through the Texas Medicaid program, which is funded in part by funds from the United States Government.

8. In order to obtain PediaSure® in meeting his son's nutritional needs, Mr. Sanchez places orders for the benefit of his son through Texas Children's Home Health Services, Inc. (hereafter "Texas Children's" or "Medicaid Agency"), which then places an order for PediaSure® with Medline, who distributes and sells the PediaSure® to the Medicaid Agency.

9. The PediaSure® received by Mr. Sanchez' son is assembled, distributed and shipped by the Defendants in case lots of twenty-four cans which are shrink wrapped in plastic wrap supported on the bottom by a cardboard carton. Multiple cases of PediaSure® are routinely received in a single monthly shipment for consumption by Mr. Sanchez' son. These shipments are transported from a Medline distribution center directly to the Sanchez residence.

10. Beginning on or about February 16, 2005, and which became more apparent beginning in March and April, 2005, Mr. Sanchez began to receive the monthly PediaSure® orders from the Defendants in a damaged condition with the damaged and dented cans of PediaSure® often being concealed on the interior of the case lots.

11. Since that time, most shipments of the PediaSure® received by Mr. Sanchez have contained damaged and dented cans concealed on the interior of the case lots with the exterior cans of the case being undamaged and not dented. The cases remained shrink wrapped with a plastic covering and protected on the bottom by cardboard which made it difficult, if not impossible, to see the damaged goods hidden on the inside of the packaged case.

12. Up to the present time, Mr. Sanchez continues to receive damaged shipments of PediaSure® cans, all having the same pattern of damage, namely, the exterior cans being undamaged and the interior cans in the cases being hidden and damaged as described above.

13. According to information contained on a website sponsored by Abbott and in other food safety-related information, damaged or dented cans are to be disposed of and not consumed. As a consequence, these cans must be thrown away or otherwise disposed of without the patient or the Texas Medicaid Program receiving the benefit of suitably usable enteral nutritional supplement for which payment has been made.

14. Due to the repetitive nature of the damaged goods being contained in what is essentially enclosed protective packaging, the damaged cans of PediaSure® have been intentionally assembled, packaged and distributed in such a fashion so as to hide the damaged cans in the case lots distributed to Medicaid recipients whose Medicaid agency is paying the full price for undamaged and merchantable goods, all while damaged goods, which are substandard or inferior, are being received on a monthly basis by the Medicaid plan patient who is the intended consumer of the enteral nutritional supplement. The Defendants' pattern and practice of secretly providing damaged, substandard and inferior goods is fraudulent and contrary to law and to the contract existing between one or more of the Defendants and the Texas Medicaid program and similarly situated programs that receive and/or use federal funds to pay for such goods.

15. Because these above-described damaged goods were sold, distributed and shipped as part of the Texas Medicaid program, a portion of the cost of these goods have been paid from funds belonging to the United States Government.

16. Mr. Sanchez is the first person to report this fraud to the appropriate authorities and is fully cooperating with those authorities.

COUNT I

17. Plaintiff/Relator incorporates herein by reference each and every allegation set forth in paragraphs 1 through 16 as though fully set forth herein.

18. As more fully described above, Defendants have submitted invoices and/or caused invoices to be submitted for payment to the Texas Medicaid Agency for PediaSure® that was in a substandard condition for purposes of obtaining funds from the Texas Medicaid Agency in order to pay for the shipments of PediaSure® to be consumed by Medicaid recipients in the state of Texas and elsewhere. The federal government, through the United States Treasury, has paid the Defendants on these false and fraudulent claims. On information and belief, the Relator alleges that Defendants' false claims are not limited to the Texas Medicaid Agency and the false claims may not be limited to PediaSure®, as they may also be related to Ensure® and other nutritional products manufactured and/or distributed by Defendants.

19. Defendants, jointly and severally, have knowingly made, used or caused to be made or used false records and statements to the United States Government, which constitute false claims under the Federal False Claims Act, and they have supplied substandard or inferior products from those contracted for in order to have the substandard or inferior products paid for and approved by the United States Government in violation of the False Claims Act, all of which has caused damage to the United States Government.

20. Defendants (a) had actual knowledge of the false information, i.e., that substandard or inferior products were being intentionally hidden from view in packaging and shipping to cause the United States Government to pay out monies it was not obligated to pay; (b) acted in deliberate ignorance of the truth or falsity of the information, i.e., deliberately chose to ignore the condition of said products; and/or (c) acted in reckless disregard of the truth or falsity of the information, i.e., recklessly disregarded the condition of said products.

COUNT II

21. Plaintiff/Relator hereby incorporates herein by reference each and every allegation contained in paragraphs 1 through 20 as though fully set forth herein.

22. The Defendants, their officers, employees and agents, have conspired with each other and created a scheme to submit and/or to cause to be submitted false claims for substandard or inferior goods described above. In furtherance of this scheme, the Defendants have submitted and/or caused to be submitted claims to Texas

Medicaid and, on information and belief, other Medicaid agencies and other federally funded programs, charging for substandard or inferior goods for the purpose of obtaining funds from said federal government agencies and/or programs. The government, through the United States Treasury, has paid the Defendants on these false and fraudulent claims.

23. As a result of these actions, Defendants have conspired to defraud the United States by submitting and/or causing to be submitted false or fraudulent claims to the United States of America, and have proximately caused damage thereby.

WHEREFORE, Plaintiff/Relator prays for judgment against the Defendants and each of them as follows:

- a. Judgment against the Defendants for violation of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*;
- b. Civil penalties for each violation of the False Claims Act, 31 U.S.C. §3729, *et seq.*;
- c. Treble damages;
- d. An award to the Relator for the maximum amount allowed under the False Claims Act or other applicable law;
- e. Reasonable attorneys fees and costs to be awarded to the Relator as allowed under the False Claims Act or other applicable law; and
- f. Any other legal or equitable remedy the Court deems just and equitable under the circumstances.

Respectfully Submitted,



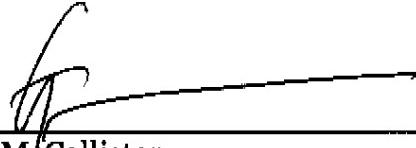
Gary D. McCallister
Thomas A. Kelliher
Jamie G. Goldstein
Gary D. McCallister & Associates, Ltd.
120 North LaSalle Street, Suite 2800
Chicago, IL 60602
(312) 345-0611 (312) 345-0612 (Fax)

Pamela B. Slate
Slate Kennedy LLC
P.O. Box 388
Montgomery, AL 36101
(334) 262-3300 (334) 262-3301 (Fax)
Attorneys for Plaintiff/Relator

Of Counsel:
Kristen Capps
Attorney at Law
Texas Bar Number 24043594
U. S. Southern District of Texas Bar No. 38742
16422 Stuebner Airline
Spring, TX 77379
(281) 258-6689 (832) 217-3199 (Fax)

DEMAND FOR JURY TRIAL

Plaintiff/Relator demands a trial of all issues of fact to be made to a jury.



Gary D. McCallister
One of the Attorneys for Plaintiff/Relator

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION**

UNITED STATES OF AMERICA,)	
<i>ex rel.</i> , RICHARD SANCHEZ,)	
)	
Plaintiffs,)	Civil Action No.
)	
)	
vs.)	Filed In-Camera and Under Seal
)	
ABBOTT LABORATORIES, INC., d/b/a)		JURY TRIAL DEMANDED
ROSS PRODUCTS DIVISION OF)		
ABBOTT LABORATORIES, INC.)		
and MEDLINE INDUSTRIES, INC.)		
)	
Defendants.)	
 STATE OF TEXAS)	
)	SS
COUNTY OF HARRIS)	

**WRITTEN DISCLOSURE OF RICHARD SANCHEZ OF SUBSTANTIALLY
ALL MATERIAL EVIDENCE AND INFORMATION**

The affiant, Richard Sanchez, having been duly sworn upon oath, affirms and states as follows:

1. My name is Richard Sanchez. I am over 18 years of age, of sound mind, and fully competent to make this affidavit. I have personal knowledge of the facts stated herein and they are all true and correct.

2. I am fifty-two years of age. I reside in Harris County, Texas. I am the father of Alec Robert Sanchez, a male child of twelve years of age. Alec has cerebral palsy and failure to thrive. He has had two fundoplication surgeries on his esophagus for projectile vomiting. He is unable to swallow food. He receives all of his nutrition via a gastrostomy button (g-button) with a feeding tube, which is a way of feeding him

EXHIBIT

A

directly into his stomach to avoid complications of projectile vomiting. He has used the feeding tube since approximately seven months of age. He cannot speak, toilet himself, dress himself, bathe himself, or walk.

3. All of Alec's nutrition comes from the product PediaSure® Enteral Formula (hereafter "PediaSure®"), manufactured by Ross Products, a Division of Abbott Laboratories. He has consumed this product since 2001. He has consumed some form of PediaSure® since he was approximately four and one - half years of age. He has no other source of nutrition except for water that he receives by mouth in very small quantities. My son's physician, Pediatric Gastroenterologist G.S. Gopalakrishna, M.D., has told me that there is no other product suitable for my son's consumption.

4. My understanding is that PediaSure® is delivered to our residence by United Parcel Service directly from Medline, a supplier, which maintains a warehouse in San Antonio, Texas. The product is ordered for my son Alec through and by Texas Children's Home Health Services, Inc., a Division of Texas Children's Hospital. Texas Children's Home Health Services orders the product, but it generally does not take possession of the PediaSure®. The product is paid for by the federally funded Texas Medicaid program, for which my son qualifies due to his severe disability. Alec currently receives nine cases comprised of twenty-four cans of PediaSure® per month.

5. On or about February 18, 2005, I received a shipment of PediaSure®. Later, on or about March 31, 2005, I was opening a case of PediaSure® from the February, 2005 shipment to feed a can to my son. I noticed mold growing on the can lid. I complained to the FDA about this mold contamination on or about April 18, 2005 because I was concerned about the contamination of the formula I was feeding my son. I have not heard back from the FDA about any disposition being made of my

complaint. Photos of this can are attached and contained in Disk 2 - Folder 1.

6. In addition to the mold, several of the cans in the case were dented. The dented cans were positioned in the middle of the case. There was no damage to the outside of the case that would have indicated to me that the damage occurred during shipment as opposed to during manufacturing or packaging of the product before shipment. Photos of these cans are attached and contained on Disk 1 in Folder 1.

7. Every month thereafter, we have continued to receive dented cans of PediaSure®. The rate of damaged or dented cans has typically ranged from a few cans in a shipment to a much larger percentage of a shipment. The dented cans are often located in the middle of the case without any sign of damage to the outside of the case.

8. On or about April 18, 2005, one of my son's teachers or aides at Wilkerson Elementary School in Conroe Independent School District in The Woodlands, Texas, sent home some dented cans of formula with a note to me indicating that she had found these cans to be dented and she did not trust them.

9. On or about April 22, 2005, my wife, Tuulia Bramlett, called me to the kitchen to look at the number and location of dented cans in the case of formula she was opening.

10. On April 24, 2005, I opened another case and saw that six of twenty-four cans were dented. I noticed that the cans were in the middle of the case without the adjacent cans on the outside of the case being dented and without any damage to the packaging that would lead me to believe they were damaged during shipment. I also noted that the batch numbers on the cans appeared to be different on cans within the same case.

11. On April 25, 2005, Texas Children's Home Health sent a delivery truck to

my home with three cases of formula to replace the dented cans. These replacement cases were in an acceptable condition with the exception of two dented cans. Photos of these cans are attached and contained on Disk 1 in Folder 2.

12. On or about April 26, 2005, I had a visit with my son's pediatric gastroenterologist, Dr. Gopalakrishna. He told me that dented cans may allow air spores to enter the formula through tiny holes that are not visible to the eye. He recommended testing a severely dented can I showed him. On or about May 13, 2005, I noticed some other dented cans from that same shipment.

13. On or about June 2, 2005 I authorized my attorneys to submit to EMSL Testing Laboratories in Houston, Texas dented cans of PediaSure® to be tested for contamination. See photos of the cans attached and contained on Disk 2 in Folder 1. The results of the testing, including the protocol used for the testing and the chain of custody form, are attached and contained on Disk 1 in Folder 3. The test results reported on July 18, 2005 showed contamination of certain identified cans that were supplied by Abbott Laboratories through its Division, Ross Products, for consumption by my disabled son.

14. In August 2005, I began tracking each shipment of PediaSure® to identify exactly where the dented cans were located within each case. I use a numbering system, assigning each case a number and each can within a case a number from one to twenty-four. A template of the numbering system is attached and contained on Disk 1 in Folder 4. I have used this tracking system most months to identify the number and location of dented cans in the shipments I have received. I have saved every dented can I have identified. In the past eighteen months, I have been shipped hundreds of dented cans that I have accumulated and retain under my

custody and control.

15. On or about June 13, 2005, I opened two cases of formula with three dented cans.

16. On July 13, 2005, I received a shipment of seven cases of twenty-four cans that contained nineteen dented cans of PediaSure®. One case contained seven dented cans and two cases contained five dented cans. Photos of these cans are attached and contained on Disk 1 in Folder 5.

17. On or about July 26, 2005, I called Texas Children's Home Health to ask them to replace the dented cans. They sent one case of PediaSure® over by Jay-Byrd Delivery Service. Seventeen of the replacement cans were dented in one case of twenty-four cans. Photos of these cans are attached and contained on Disk 1 in Folder 6. I had the delivery driver, Monet, witness and sign on the receipt that fifteen of the cans were dented, but my wife later discovered more dented cans in the replacement case. The Jay-Byrd driver informed me the case was transported to my house on the front seat of her vehicle.

18. On either August 12 or 15, 2005, I received a shipment of four cases of twenty-four cans each with three dented cans. Photos of these cans are attached and contained on Disk 1 in Folder 7.

19. On or about September 16, 2005, I received a shipment of seven cases of twenty-four cans each. In that shipment, ten cans were dented. Photos of these cans are attached and contained on Disk 1 in Folder 8.

20. On or about October 13, 2005, I received a shipment of nine cases of twenty-four cans each. In that shipment, thirty-six cans were dented. Photos of these cans are attached and contained on Disk 1 in Folder 9.

21. On or about November 15, 2005, I received a shipment of nine cases of twenty-four cans with thirty-five dented cans. Photos of these cans are attached and contained on Disk 1 in Folder 10.

22. On or about December 23, 2005, I received a shipment of nine cases of twenty-four cans each. In that shipment, eighteen cans were dented.

23. On or about March 21, 2006, I received a shipment of PediaSure® that contained nine cases of twenty-four cans. In that shipment, one case of twenty-four cans had six dented cans, one case had five dented cans, and one case had ten dented cans. Photos of these cans are attached and contained on Disk 1 in Folder 11.

24. On or about May 25, 2006, I received a shipment of nine cases of twenty-four cans. Thirteen cans in this shipment were damaged. One case of twenty-four had four dented cans. Photos of these cans are attached and contained on Disk 1 in Folder 12.

25. On or about June 27, 2006, I received a shipment of nine cases of twenty-four cans. In that shipment, fifty-one cans were dented. One case had twelve of twenty-four cans dented. Photos of these cans are attached and contained on Disk 1 in Folder 13.

26. On or about July 28, 2006, I received a shipment of eight cases of twenty-four cans of PediaSure®. Twelve cans in this shipment were dented. In one case, five cans of twenty-four were dented. Photos of these cans are attached and contained on Disk 1 in Folder 14.

27. On or about August 26, 2006, I received a shipment with fifty-four dented cans, including one case in which every can had damage on the top of the can. The outside packaging did not show any damage. Two other cases each contained eight

dented cans. Photos of these cans are attached and contained on Disk 1 in Folder 15.

28. On or about September 26, 2006, I received a shipment of nine cases containing twenty-two dented cans. One case of twenty-four had nine dented cans. Another case of twenty-four contained seven dented cans. Photos of these cans are attached and contained on Disk 1 in Folder 16.

29. On or about October 29, 2006, I received a shipment of nine cases of twenty-four cans of PediaSure®. In this shipment, fifty-five cans were dented. Photos of these cans are attached and contained on Disk 1 in Folder 17.

30. On or about November 29, 2006, I received a shipment of nine cases of twenty-four cans of PediaSure®. When I opened the cases on December 4, 2006 thirty-two cans in this shipment were dented and many of the cans had a dark substance on the lids of the cans. Photos of these cans are attached and contained on Disk 1 in Folder 18.

31. On or about December 29, 2006, I received a shipment of nine cases of twenty-four cans of PediaSure®. When I opened the cases on January 1, 2007, thirty-four cans in this shipment were dented. Photos of these cans are attached and contained on Disk 1 in Folder 19.

32. Due to the contamination of the product shipped to my son and my concern for his safety arising from his ingestion of contaminated formula as stated above, I began to research food adulteration safety issues, the potential adverse effects of consuming dented cans, and charges that may have been leveled against Abbott Laboratories and its subsidiaries, including Ross Products. As a result of this research, on April 4, 2005, I found a reference to a Houston Chronicle article dated May 27, 2004, relating to a lawsuit by the State of Texas against Abbott Laboratories, Baxter

International, and B. Braun Melsungen for allegedly charging inflated prices to Medicaid patients. This reference is attached and contained on Disk 3 in Folder 1. Around this time, I searched for the pricing of PediaSure® and found it was available on the internet for less than forty dollars (\$40.00) per case. Upon information and belief, Medicaid has been charged from \$88.00, \$92.00 and now \$100.00 per case for the same product for my son. I have since learned that the Office of the Inspector General conducted an investigation in which it concluded that Medicare was being overcharged for products similar to PediaSure®. This reference is attached and contained on Disk 3 in Folder 2.

33. As a result of looking at food safety and adulteration issues, I found references stating dented cans were not suitable for human consumption. One source said that when a dent occurs near a seam or junction of the can, a dent can make it possible for air to enter the can, allowing the growth of microorganisms. A University of Missouri web site said that “[a] can that is so bent that the metal is creased is much more likely to develop a small pinhole leak than a can that has a slight dent.” This reference is attached and contained on Disk 3 in Folder 3. I also found an experiment sponsored by the Discovery Center Museum in which it could be demonstrated that an acidic substance in a dented can could cause an electric current that interacted with the food in the can, dissolving the metal on the can and causing it to enter the food. This reference is attached and contained on Disk 3 in Folder 4.

34. Most notably on April 22, 2005, I found on a web site for new parents using infant formula sponsored by Abbott Laboratories and its subsidiary, Ross Products, the following question being asked: “Is it okay to use formula that comes from dented cans?” Ross Products stated on its website, in answer to that question:

"No, the safety of the formula may be affected by tiny openings caused by the dent." It is interesting to note this warning has not appeared anywhere on the labels on the cans we have received from Ross Products to the best of my knowledge. This reference is attached and contained on Disk 3 in Folder 5.

35. On or about May 2, 2005, I read an article on line related to an MSNBC investigation of school cafeterias in Fairfax, Virginia. The article cited dented cans as a "critical violation" found by the health inspector in two Fairfax County Schools. The article said "a dented or swollen can, especially one with a broken seal, could lead to the growth of dangerous bacteria inside the can. This reference is attached and contained on Disk 3 in Folder 6.

36. In the late spring of 2005, I learned one of Abbott Laboratories subsidiaries agreed to plead guilty to a felony of obstructing the criminal investigations of health care offenses and pay a criminal fine of \$200,000,000 and restitution in the amount of \$200,000,000 relating to the government's investigation into the company's sales practices for "liquids used to feed the seriously ill." This was confirmed by the entry of a plea agreement as to CG Nutritionals, Inc. on July 23, 2003 in the United States District Court for the Southern District of Illinois and a Stipulation of Facts as to CG Nutritionals, Inc. in Case# 3:03-CR-30144-GPM-ALL. The Plea Agreement and Stipulation of Facts are attached and contained on Disk 3 in Folder 7. As a result of the Plea Agreement, Abbott Laboratories including Ross Products Division, was required to enter into a five-year Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services related to its sales and marketing practices. A copy of the Corporate Integrity Agreement is attached and contained on Disk 3 in Folder 8.

37. Between approximately April 2005 and June 2005, I read information contained in an Abbott report in which Abbott Laboratories trumpeted the cost savings it had achieved by reducing the thickness of the cans in which their nutritional products were contained. This article is attached and contained on Disk 3 in Folder 9. Over the years of receiving the product, I have noticed changes in the way the product is packaged. These changes to the packaging and the reduced thickness of the steel cans may also be contributing to the damage to the cans.

38. Between April 2005 and June 2005, I found an article by Alan Crawford, Senior Project Leader at Ross Products Division of Abbott Laboratories, about how Abbott Laboratories used a random vibration test and drop testing to test new packaging of its products for club stores. One of these products is Glucerna®, a product packaged in steel cans similar to the cans used in PediaSure®. The article also discusses the use of spot checks in the field to check for "package appearance" and cites "no damage complaints" related to the products in the article. This reference is attached and contained on Disk 3 in Folder 10.

39. In the summer of 2005, my child's former nurse, Nona Basso, told me she had another patient who received Ensure®, manufactured by Abbott Laboratories Division, Ross Products. Upon information and belief, this product has also been known to arrive with dented cans in the package. I do not know the name of the family or the frequency that they receive dented cans.

40. On or about August 16, 2006, one of my child's nurses, Tamisha Pate, told me that she encounters dented cans of PediaSure® frequently with her other patients. She removed two other cans that we had missed that were dented.

41. I am convinced based on my personal experience that Abbott

Laboratories, its division, Ross Products, and Medline are knowingly distributing substandard and damaged product to my child and others dependent on tube feeding through the Texas Medicaid program as well as other Medicaid programs in the various states. The persistence of the damaged cans being hidden in the middle of cases of enteral formula I have received month after month that are not damaged on the perimeter of the cases convinces me Abbott Laboratories, Ross Products Division and Medline are intentionally concealing damaged or substandard goods that are sold to Medicaid agencies at premium prices as described above. Abbott has admitted on its own web site that dented cans are unsuitable for consumption, yet every month, my son, a Medicaid patient, receives Abbott's damaged and defective product that might make him sick. The manner in which the dented and contaminated cans are arranged in the shrink wrapped cases I have been receiving for the past two years cannot possibly be missed if any reasonable quality control program is utilized by Ross Products Division and Medline. The repeated manner in which these substandard goods have been sent to us suggests that there has been intentional conduct in secreting these dented and contaminated cans in the center of cases placed for shipment for which overcharging to Medicaid agencies may be occurring. Such fraudulent and intentional conduct is not foreign to Abbott Laboratories and Ross Products Division and may well violate the spirit and letter of paragraph 16 of the above described Plea Agreement in which Abbott and Ross Products agreed not to commit any offense in violation of federal, state or local law during the five (5) year probation period imposed by the Plea Agreement and the Corporate Integrity Agreement which is attached and incorporated into this written disclosure. The victims of this scheme are the Medicaid agencies that are being overcharged and consumers

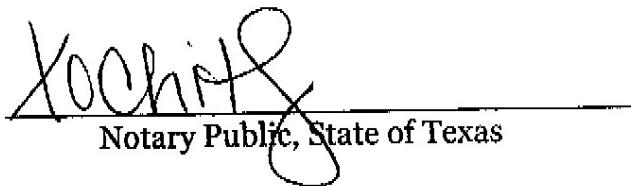
like my son who is indigent and seriously ill and do not have the ability to change to alternative nutritional products when they are supplied substandard or adulterated food products. Based on the above and foregoing I have decided to refer this matter to the government for investigation pursuant to The False Claims Act, 31 U.S.C. §3729 *et seq.*

FURTHER AFFIANT SAYETH NOT.



Richard Sanchez

SUBSCRIBED & SWORN TO
Before me this 14 day of February, 2007.



Xochitl Valdez
Notary Public, State of Texas

